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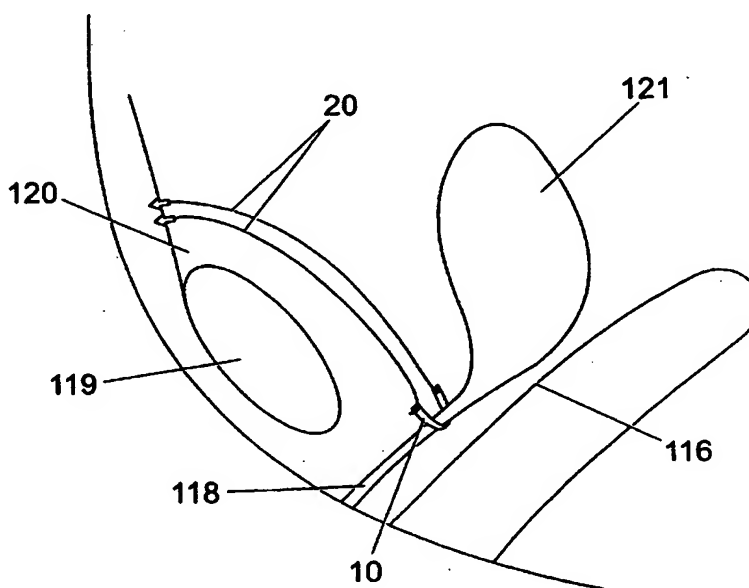
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- (71) Applicant (for all designated States except US): **GYNE IDEAS LIMITED [GB/GB]; 1 Bell Leys, Wingrave, Buckinghamshire HP22 4QD (GB).**
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **BROWNING, James [GB/GB]; 12 Sherbrooke Gardens, Glasgow G41 4HU (GB).**
- (74) Agent: **MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB).**
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[Continued on next page]

(54) Title: **APPARATUS AND METHOD FOR TREATING FEMALE URINARY INCONTINENCE**



(57) Abstract: The present invention provides a surgical implant and method for supporting the urethra (118), the implant comprising: a suburethral support (10) suspended between two soft tissue anchors (30) that do not penetrate the lower abdominal wall and are attached at either side of the suburethral support (10). The soft tissue anchors (30) retain each anchor in soft tissue, suspending each side of the suburethral support (10). The suburethral support (10) passes under the urethra (118) to support the urethra (118). The implant has uses including treating urinary incontinence and uterovaginal prolapse.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1 **"Apparatus and Method for Treating Female Urinary**
2 **Incontinence"**

3
4 This invention relates to an apparatus and method
5 for treating female urinary incontinence and, in
6 particular, to a surgical implant having a sling
7 that passes under the urethra in use and supports
8 the urethra to alleviate incontinence, along with
9 related apparatus and methods for inserting the
10 surgical implant in the body.

11
12 Urinary incontinence affects a large number of women
13 and, consequently, various approaches have been
14 developed to treat female urinary incontinence.
15 Those skilled in the art will be familiar with
16 approaches ranging from pelvic floor exercises to
17 surgical techniques such as Burch colposuspension
18 and Stamey-type endoscopic procedures in which the
19 sutures are placed so as to elevate the bladder
20 neck.

21

1 This invention is particularly directed to
2 improvement of a known procedure in which a sling is
3 positioned loosely under the urethra, commonly known
4 as TVT (tension free vaginal tape) and described,
5 for example, in International Patent Applications
6 No. WO97/13465 and WO97/06567. It is generally
7 understood that this treatment alleviates urinary
8 incontinence by occluding the mid-urethra (for
9 example at a time of raised abdominal pressure by
10 coughing or the like).

11

12 The sling is provided in the body using two large
13 curved needles which are provided at each end of the
14 sling, which sling comprises a long mesh or tape.
15 Each of the needles is carried on an insertion tool
16 (which is basically a handle facilitating
17 manipulation of the needles). The mesh or tape is
18 usually made of knitted polypropylene (such as
19 Prolene®). The mesh or tape is generally covered
20 with a plastics sleeve or polythene envelope to aid
21 smooth insertion, the mesh or tape having rough
22 surfaces to aid retention in the body.

23

24 An incision is made in the anterior vaginal wall and
25 the first of the needles is passed through the
26 incision, past one side of the urethra, behind the
27 pubic bone, through the rectus sheath and out
28 through the lower anterior abdominal wall.

29 Likewise, the second needle is passed through the
30 incision, past the other side of the urethra, behind
31 the pubic bone, through the rectus sheath and out
32 through the lower abdominal wall. The needles are

1 separated from their respective insertion tools and
2 also from the mesh or tape such that only the tape
3 and its plastics sleeve are left in the body,
4 passing from a first exit point in the lower
5 abdominal wall, through the rectus sheath, behind
6 the pubic bone, under the urethra, back behind the
7 pubic bone, back through the rectus sheath and out
8 through a second exit point in the lower abdominal
9 wall.

10

11 The plastics sleeve is then removed from the tape
12 and the tape adjusted to a suitable tension (such
13 that the tape provides a sling that passes loosely
14 under the urethra, as described above) by
15 manoeuvring the free ends of the tape outside the
16 exit points in the lower abdominal wall whilst the
17 urethra is held using a rigid catheter inserted
18 therein. The tape is then cut such that it just
19 falls short of protruding from the exit points in
20 the lower abdominal wall. The exit points and the
21 incision in the upper vaginal wall are then closed
22 by sutures. The tape is held in position by virtue
23 of friction between the tape's rough edges and the
24 surrounding body tissue (such as the rectus sheath
25 and the body tissue behind the pubic bone) and
26 subsequent natural adhesion of the tape with the
27 body tissue as it re-grows around the mesh material.
28 Whilst highly effective in treating urinary
29 incontinence, this procedure has a number of
30 problems. One such problem is that the needles used
31 for inserting the tape are comparatively large, with
32 the needles having, for example, a diameter of

1 around 5-6 mm and a length of around 200 mm. As
2 well as causing concern for patients viewing such
3 needles before or during the procedure (which is
4 carried out under local anaesthetic), this can also
5 lead to a high vascular injury rate.

6
7 Similarly, the requirement that the needles exit the
8 lower abdominal wall is disadvantageous due to the
9 trauma to the patient in this area and pain of such
10 abdominal wounds. A further disadvantage is that
11 the tape comprises a relatively large foreign body
12 mass to be retained within the patient and this can
13 lead to related inflammation, infection
14 translocation, erosion, fistula and such like.

15
16 Similarly, the nature of the large needles and tape,
17 along with the tools required to insert these in the
18 body, lead to the procedure having a relatively high
19 cost.

20
21 According to a first aspect of the present invention
22 there is provided a surgical implant for supporting
23 the urethra, the implant comprising: a suburethral
24 support suspended between at least two soft tissue
25 anchors attached at either side of the suburethral
26 support, each soft tissue anchor having retaining
27 means for retaining each anchor in tissue and
28 suspending means for suspending each side of the
29 suburethral support from a soft tissue anchor such
30 that the suburethral support passes under the
31 urethra in use.

32

1 Preferably the retaining means of the soft tissue
2 anchor is capable of being inserted into soft tissue
3 or fascia from an incision in the upper vaginal wall
4 without the need to penetrate the lower abdominal
5 wall.

6
7 In one embodiment the soft tissue anchor is
8 insertable into the rectus sheath of the human or
9 animal body to anchor suspending means to the soft
10 tissue, the suspending means being attached to the
11 soft tissue anchor and the soft tissue anchor having
12 retaining means adapted to prevent retraction of the
13 anchor from the rectus sheath in a direction
14 opposite to that of insertion of the anchor into the
15 tissue.

16
17 Preferably the soft tissue anchor comprises a
18 central portion and the retaining means includes at
19 least one wing section, the wing section being
20 mounted on a first end of the central portion by
21 resilient hinge means such that the wing section is
22 moveable between an open, resting position and a
23 deflected position such that in use, when the soft
24 tissue anchor device is inserted into the tissue the
25 wing section is pushed or held towards the central
26 portion to a deflected position to permit entry of
27 the soft tissue anchor into the tissue and through
28 the rectus sheath, wherein the wing section returns
29 to its open or resting position and prevents the
30 soft tissue being removed.

31

1 Preferably the resilient hinge means allows the wing
2 section to return to its resting position from its
3 deflected position following penetration of the soft
4 tissue anchor through the rectus sheath such that
5 the wings of the soft tissue anchor once pushed
6 through the rectus sheath can rest on the surface of
7 the rectus sheath fascia opposite to the surface
8 through which the soft tissue anchor is inserted and
9 thus the soft tissue anchor cannot be retracted.

10

11 Preferably the resilient hinge means is capable of
12 preventing the wing section being moved to a
13 position greater than substantially perpendicular to
14 the central portion.

15

16 Preferably the central portion of the soft tissue
17 anchor comprises a hollow passage which extends from
18 a first end of the central portion to a second
19 opposite end of the central portion.

20

21 Preferably an introducing tool can be placed into
22 the hollow passage such that the introducing tool
23 extends through the central portion the soft tissue
24 anchor such that the introducing tool extends to a
25 point beyond the first end of the central portion.

26

27 Preferably the soft tissue anchor comprises a
28 plurality of wing sections.

29 More preferably the soft tissue anchor comprises
30 four wing sections arranged radially around the
31 first end of the central portion.

32

1 Preferably the soft tissue anchor in addition to
2 comprising a central portion and a wing section also
3 comprises at least one stud element arranged
4 radially around the first end of the central
5 portion, the stud having an inclined face in the
6 opposite direction to that in which the soft tissue
7 anchor is inserted to aid separation of the tissue
8 during entry of the soft tissue anchor enabling
9 easier passage of the soft tissue anchor through the
10 soft tissue.

11
12 Preferably the soft tissue anchor does not comprise
13 a sharp point.

14
15 In an alternative embodiment the soft tissue anchor
16 is capable of anchoring in the retropubic tissue
17 space without penetrating the rectus sheath.

18
19 Preferably the soft tissue anchor in this embodiment
20 permits fixation at multiple points via a christmas
21 tree type configuration of deflectable wings.

22
23 A soft tissue anchor according to this embodiment
24 comprises a central portion and the retaining means
25 includes a plurality of projections the projections
26 extending radially from the central portion along a
27 substantial portion of the length of the central
28 portion allowing fixation at a plurality of layers.

29 Preferably the projections extend radially from the
30 central portion at an angle inclined toward the
31 second end of the central portion.

32

1 Preferably the projections are of a shape that they
2 are able to provide additive traction to the soft
3 tissue anchor and allow it to grip fibro-fatty soft
4 tissue and blood vessels of the para-urethral
5 tunnel below the level of the rectus sheath.

6
7 In yet a further embodiment the soft tissue anchor
8 may comprise a substantially flat head the bottom
9 surface nearest the suspending means of the flat
10 head providing the retaining means which, in use is
11 held in the rectus sheath.

12
13 In a further embodiment the soft tissue anchor may
14 comprise a sharp point allowing it to pierce or
15 penetrate the rectus sheath, and retaining means
16 comprising a surface or protrusion directed
17 rearwardly with respect to the sharp point which
18 does not cause the soft tissue to part and thus
19 prevents the soft tissue anchor from being pulled
20 back out through the rectus sheath soft tissue in
21 the direction opposite to that in which it is
22 inserted into the soft tissue.

23
24 Preferably the sharp point is provided by the apex
25 of a conical head portion and retaining means are
26 provided by a substantially flat base of the conical
27 head.

28
29 In any embodiment the soft tissue anchor is
30 comprised of plastics material.

31

1 Typically the soft tissue anchor is comprised of
2 polypropylene.

3
4 Alternatively the soft tissue anchor is comprised of
5 absorbable material so as to form temporary fixation
6 in soft tissue.

7
8 The soft tissue anchor may comprise a point formed
9 of absorbable material including polyglactin, the
10 sharp point thus capable of facilitating insertion
11 of the anchor, yet being absorbed by the body later.

12
13 Preferably the soft tissue anchor may be integral
14 with the suspending means.

15
16 More preferably the soft tissue anchor is integrally
17 formed from polypropylene or other polymeric
18 material the attachment between the anchor and the
19 suspending being formed as a single unit.

20
21 An integral construction of the soft tissue anchor
22 and suspending means has the advantage of
23 simplifying the construction of the soft tissue
24 anchor and suspending means, which can reduce the
25 possibility of defective manufacture etc. and reduce
26 costs and the chance of the soft tissue anchor and
27 suspending means becoming detached once implanted in
28 the body.

29
30 Alternatively the soft tissue anchor is attached to
31 the suspending means by a thin metal tube crimped or

1 otherwise attached around the suspending means and
2 central portion of the soft tissue anchor.

3

4 The suburethral support of the first aspect of the
5 invention passes under the urethra, loosely
6 supporting the urethra, the suburethral support
7 being held in position by suspending means attached
8 to each of its free ends on either side of the
9 urethra, the suspending means being attached at the
10 opposite end to at least one soft tissue anchor.

11

12 Preferably the suburethral support is comprised of
13 flat polymer tape.

14

15 Preferably the suburethral support has dimensions
16 sufficient only to pass around the urethra.

17

18 More preferably the suburethral support has
19 dimensions of length 15-35mm, width 5-15mm and
20 thickness 50-350 μ m.

21

22 In one embodiment the suburethral support has
23 dimensions of length 25mm, width 10mm and thickness
24 100 μ m.

25

26 Preferably the suburethral support has at least two
27 junctions to attach the suburethral support to the
28 suspending means.

29

30 One problem with the preferred arrangement of a soft
31 tissue anchor and suspending means for suspending
32 the suburethral support of the surgical implant of

1 the invention is that it is difficult to
2 predetermine what length the suspending means must
3 be to position the suburethral support loosely under
4 the urethra as desired.

5
6 This is because the distance between the rectus
7 sheath in which the soft tissue anchor is inserted
8 and the urethra varies from patient to patient.

9
10 Preferably the distance between the soft tissue
11 anchor(s) and the suburethral support is adjustable.

12
13 More preferably the soft tissue anchor (or anchors)
14 can be positioned first and the suburethral support
15 then positioned by adjusting the length of the
16 suspending means.

17
18 Preferably the suburethral support is provided with
19 at least one attachment tab to which suspending
20 means are releasably or permanently attached.

21
22 Preferably the suburethral support comprises an
23 attachment tab comprising a tunnelled element and an
24 aperture, the tunnelled element being located at
25 each of the free ends of the suburethral support on
26 either side of the urethra at a position that the
27 suspending means are capable of being introduced
28 through, the tunnelled element co-operating with the
29 aperture such that suspending means can be passed
30 through the tunnelled element and then through the
31 aperture, the aperture being present on the opposite
32 surface of the suburethral support to that which

1 contacts the urethra the aperture having an edge
2 capable of co-operating with a ring element and the
3 ring element being capable of being fitted around
4 the aperture trapping the suspending means between
5 the ring element and the edge of the aperture such
6 that the suspending means remain fixed in an
7 adjusted position wherein the suburethra support
8 hanging loosely under the urethra.

9

10 Alternatively the attachment tab comprises at least
11 one slot through which suspending means can be
12 passed, the suspending means being permanently
13 attached to the slot by tying.

14

15 Alternatively the attachment tab comprises jamming
16 slots that the suspending means can be permanently
17 attached by being threaded through the jamming slots
18 such that the suspending means are held in an
19 adjusted position.

20

21 Alternatively the suburethral support is capable of
22 being suitably positioned under the urethra by
23 altering the position of the soft tissue anchors
24 within the body such that at least one soft tissue
25 anchor is secured in the soft tissue or in the
26 rectus sheath and a subsequent anchor is inserted
27 into the soft tissue or rectus sheath to a suitable
28 depth such that the suburethral support hangs
29 loosely under the urethra.

30

31 Alternatively the suspending means may be attached
32 to the suburethral support by healing such that the

1 suburethra support and/or suspending means melt and
2 form a join.

3
4 Alternatively the attachment tabs may have closure
5 means for gripping the suspending means.

6
7 The suspending means may be any means suitable for
8 connecting each end of the suburethra support to the
9 soft tissue anchor (or respective soft tissue
10 anchors).

11
12 Preferably the suspending means comprises a plastics
13 strip.

14
15 Preferably the plastics strip has smooth edges.

16
17 Preferably the plastics strip comprises material
18 such as polypropylene or other suitable non-
19 absorbable or absorbable polymer tape.

20
21 Preferably the plastics strip is 3-5mm in width.

22
23 Preferably the plastics material comprises pores
24 which extend through the plastics material from a
25 first surface of the plastics material to a second
26 opposite surface of the plastics material said pores
27 ranging in width across the surface of the plastics
28 material from 50 μ m to 200 μ m, the pores allowing
29 tissue in-growth to secure the strip in the body.

30
31 Alternatively the plastics material may comprise
32 pits, that indent but do not extend through the

1 plastics material, on at least one of the surfaces
2 of the plastics material, the pits ranging in width
3 from 50 μ m to 200 μ m, the pits allowing tissue in-
4 growth to secure the strip in the body.

5

6 Preferably the plastics material comprises pits or
7 pores ranging in width across the surface of the
8 plastics material from 100 μ m to 150 μ m.

9

10 Preferably the pits or pores are distributed across
11 the complete surface of the plastics material.

12

13 Alternatively the pits or pores are distributed only
14 in a particular portion of the surface of the
15 plastics material.

16

17 Preferably the pits or pores are created by post
18 synthesis modification of the plastics material.

19

20 More preferably the pits or pores are created by
21 post synthesis treatment of the plastics material by
22 a laser.

23

24 Alternatively the pits or pores of between 50-200 μ m
25 are created during synthesis of the plastics
26 material by spaces between the waft and weave of
27 mono-filament or multi-filament yarns when the
28 filaments are woven to form a mesh.

29

30 Alternatively pits or pores formed during the
31 synthesis of plastics material are formed by the
32 inter-filament spaces created when mono-filaments

1 are twisted to create multi-filaments, the multi-
2 filaments then being woven to form a mesh.

3

4 In an embodiment the suspending means is provided
5 with a plurality of microgrooves of width between
6 0.5-7 μ m and of depth 0.25-7 μ m on at least one
7 surface of the plastics strip.

8

9 Preferably the microgrooves are 5 μ m in width and 5 μ m
10 in depth.

11

12 Preferably the plurality of microgrooves are aligned
13 such that they are substantially parallel with each
14 other.

15

16 Preferably the plurality of microgrooves are aligned
17 such that they are separated by ridges which range
18 in size between 1-5 μ m in width.

19

20 More preferably the microgrooves are separated by
21 ridges of 5 μ m in width.

22

23 Preferably the ridges are formed by square pillars
24 and the base of the microgroove is substantially
25 perpendicular to the square pillars.

26

27 Alternatively the ridges are formed by square
28 pillars and the base of the microgroove is bevelled
29 in relation to the pillars.

30

31 Preferably the microgrooves are present on at least
32 one surface of the suspending means.

1 More preferably the microgrooves are present on a
2 plurality of surfaces of the suspending means.

3

4 These microgrooves act to orientate and align the
5 proliferating fibroblasts on the surface of the
6 plastics material and cause axial alignment of
7 collagen fibres and formation of at least one strong
8 ordered neoligament.

9

10 The orientation and alignment of the proliferating
11 cells is capable of adding mechanical strength to
12 the tissue which forms around the plastics material
13 such that it is more able to support the urethra.

14

15 Preferably the suburethral support of the present
16 invention has neither pores, pits or grooves to
17 discourage the formation of peri-urethral adhesions.

18

19 According to a second aspect of the present
20 invention there is provided a method of supporting
21 the urethra comprising the steps of, introducing a
22 surgical implant as described above into an incision
23 made on the upper wall of the vagina, inserting a
24 soft tissue anchor on a first side of the urethra
25 behind the pubic bone, inserting a second soft
26 tissue anchor on a second side of the urethra behind
27 the pubic bone, such that the suburethral support is
28 suspended from the soft tissue anchor supports the
29 urethra.

30

1 The invention also provides the use of the method of
2 supporting the urethra in treating urinary
3 incontinence or uterovaginal prolapse.

4
5 In one embodiment of the method the soft tissue
6 anchors are inserted in the rectus sheath.

7
8 In an alternative embodiment of the method the soft
9 tissue anchors are inserted in the fibro-fatty soft
10 tissue of the retropubic tissue space and do not
11 penetrate the rectus sheath.

12
13 The invention also provides an introducing tool
14 comprising an elongate housing adapted to receive
15 the soft tissue anchor at one end and a point which
16 is capable of extending through the central portion
17 of a soft tissue anchor for use in carrying out the
18 method of the invention such that the introducing
19 tool enables access and placement of the soft tissue
20 anchor through the rectus sheath or in the fibrous
21 fatty soft tissue of the para-urethral tunnel from
22 an insertion point in the upper vaginal wall.

23
24 More preferably the elongate housing is curved or
25 bent, preferably through an angle of approximately
26 30°.

27
28 It is desirable such that a sharp point of an anchor
29 not is not retained in the body that the soft tissue
30 anchor may be inserted using an introducing tool the
31 introducing tool having a sharp point for
32 penetrating the soft tissue.

1 Preferably an introducing tool comprises a sharp
2 point for piercing or penetrating soft tissue and
3 carrying means for carrying the soft tissue anchor
4 to insert the anchor into the tissue such that the
5 soft tissue anchor device does not require a sharp
6 head and no sharp point is left in the body.

7
8 The overall size of the soft tissue anchor and
9 introducing tool may be significantly smaller than
10 that of the needles of the prior art.

11
12 Preferably the introducing tool may have a diameter
13 of around 2 mm to 4 mm.

14
15 Preferably if the introducing tool is to be used in
16 co-operation with a soft tissue anchor comprising a
17 plurality of projections extending radially from the
18 central portion along a substantial portion of the
19 length of the central portion of the soft tissue
20 anchor, the introducing tool comprises containment
21 means for radially confining the plurality of
22 projections extending from the central portion of
23 the soft tissue anchor during the insertion of the
24 soft tissue anchor.

25
26 Thus, when the soft tissue anchor has been inserted,
27 the tool may release the retaining means around the
28 soft tissue anchor such that the projections which
29 have memory are biased to expand radially and grip
30 the soft tissue.

31

1 The reduced size of the introducing tool in
2 comparison to the needles used to introduce devices
3 of the prior art can significantly reduce the
4 vascular injury rate and perceptual problems of the
5 prior art for a patient.

6
7 Preferably the introducing tool is able or has means
8 for releasably retaining the soft tissue anchor on
9 the end of the housing.

10
11 During the insertion of a surgical implant to
12 support the urethra there is a risk of penetration
13 of the bladder wall by the needles during insertion
14 of the tape.

15
16 This is known to be a problem with the TVT procedure
17 described by the prior art where the needles are
18 inserted through an incision in the vagina to thread
19 the tape through the respective punctures in the
20 lower anterior abdominal wall.

21
22 Following the TVT procedure of the prior art it is
23 therefore conventional to carry out cystoscopy after
24 the tape has been inserted in the body to determine
25 whether or not the bladder has been perforated.
26 This is painful for the patient and also increases
27 the duration of the operation.

28
29 The reduced size of the tools used for inserting the
30 surgical implant of the present invention reduce to
31 some degree the risk of the bladder being perforated
32 during the surgical procedure, however it is

1 nevertheless desirable to reduce the need for
2 cystoscopy.

3

4 Accordingly at least a part of the surgical implant
5 of the present invention may be coated or
6 impregnated with a water soluble dye.

7

8 Preferably the soft tissue anchor of the present
9 invention is impregnated with a water soluble dye.

10

11 Preferably, the water soluble dye is methylene blue.

12

13 It is possible to determine whether or not the
14 bladder of a patient has been perforated by a
15 surgical implant or instrument when inserting the
16 surgical implant of the invention into the body, by
17 expelling a small amount of fluid from the bladder,
18 and determining whether or not this small amount of
19 fluid contains any dissolved dye.

20

21 Should the bladder be perforated on insertion and
22 placement of the surgical implant into the body, the
23 dye impregnated into the surgical implant will
24 dissolve in the fluid contained in the bladder and
25 diffuse naturally throughout the fluid.

26

27 Thus should dye be present in the fluid, it is very
28 likely that the bladder has been perforated and
29 cystoscopy should be carried out. If there is no
30 dye in the fluid, the bladder has not been
31 perforated and the need for cystoscopy is obviated.

32

1 The soft tissue anchors as described in relation to
2 the implant of the present invention are capable of
3 use in a variety of situations.

4
5 Accordingly the invention provides soft tissue
6 anchors as described herein.

7
8 The invention also provides the use of the soft
9 tissue anchors in hernia repair, face lifts, plastic
10 surgery and cosmetic surgery.

11
12 Preferred embodiments of the present invention will
13 now be described, by way of example only, with
14 reference to the accompanying drawings, in which:

15
16 Figure 1 is an illustration of a surgical
17 implant according to the invention,

18 Figure 2 is a line drawing of the suspending
19 means attached to the suburethral support,
20 positioned underneath the urethra,

21 Figure 3 is an illustration of one embodiment
22 of a suburethral support,

23 Figure 4 is an illustration of a second
24 embodiment of a suburethral support,

25 Figure 5 shows suspending means being threaded
26 through an attachment tab of a suburethral support,

27 Figure 6A, B and C show alternative methods of
28 attaching suspending means to a suburethral support,

29 Figure 7 is an illustration of a soft tissue
30 anchor for insertion through the rectus sheath,

31 Figures 8A-C are sequential illustrations of
32 insertion of a soft tissue anchor of Figure 7,

1 Figure 9 is an illustration of a soft tissue
2 anchor mounted on an introducing tool,

3 Figure 10 is an illustration of a retropubic
4 soft tissue anchor for use in the fibro-fatty
5 tissues of the para-urethral tunnel,

6 Figure 11 is an illustration of the placement
7 of a soft tissue anchor of figure 10,

8 Figure 12 is an illustration of an implanting
9 tool and a soft tissue anchor inserted into the
10 rectus sheath,

11 Figure 13 is an illustration of the surgical
12 implant implanted into the rectus sheath,

13 Figure 14 is an illustration of the prior art
14 contrasted with the technique of the present
15 invention,

16 Figure 15 is an illustration of the tool used
17 to insert the surgical implant, and

18 Figure 16 is an illustration of the surface
19 architecture of the suspending means.

20

21 Referring to Figure 1, a surgical implant for
22 treating female urinary incontinence has a
23 suburethral support 10, suspending means 20 and at
24 least two soft tissue anchors 30, the suburethral
25 support 10 being positioned in use, loosely under
26 the urethra. The suburethral support has a length L
27 of around 25 mm and a width W of around 10 mm such
28 that it passes around the urethra with a minimum of
29 excess material, although other similar dimensions
30 would also be suitable. In this example, the
31 suburethral support 10 is made from flat polymer
32 tape. At each side 11,13 of the suburethral support

1 10 suspending means 20 are provided which attach to
2 the suburethral support 10 at a first end 22, 24.

3

4 The suspending means 20 are attached at a second end
5 26 to a respective soft tissue anchor 30.

6

7 As shown in figure 7 the soft tissue anchor 30 of
8 the embodiment described comprises a central portion
9 32 and four winged sections 34 which are attached to
10 the central portion at a first end 38 by resilient
11 hinge means 36 and radially extend from the central
12 portion 32 such that when viewed from the front the
13 anchor device resembles a cross.

14

15 As shown in figure 8A the wing sections 34 of the
16 soft tissue anchor 30 having a resting position in
17 which they are inclined towards the rear 40 of the
18 central portion 32 at an angle of around 45°. In
19 figure 8B during penetration of the anchor through
20 tissue (the point 60 of the introducing tool
21 enabling the soft tissue anchor to be pushed through
22 the tissue and rectus sheath 120) the wing sections
23 34 of the soft tissue element 30 may adopt a
24 deflected position which means the penetration of
25 the soft tissue anchor through the tissue and rectus
26 sheath 120 is more effective.

27

28 As shown in figure 8C once the rectus sheath 120 has
29 been pierced the resilient hinge means 36 cause the
30 wing sections 34 to return to their resting
31 position.

1 Movement of the soft tissue anchor in a direction
2 opposite to which it was introduced into the soft
3 tissue causes the wing section to be deflected until
4 an endstop 46 is reached which prevents the wing
5 sections 34 moving beyond a point substantially
6 perpendicular to the central portion 32 and prevents
7 retraction of the soft tissue anchor 30 from the
8 soft tissue.

9
10 The soft tissue anchor 30 further comprises a hollow
11 portion 48 which extends from the first end 38 to
12 the second rear end 40 of the central portion 32
13 through which an introducing tool 50 may be placed.

14
15 The introducing tool 50 extends through the hollow
16 portion 48 such that it extends as a sharp point 60
17 from the first end 38 of the soft tissue anchor 30
18 such that the sharp point 60 allows penetration of
19 the tissue by the soft tissue anchor 30.

20
21 Stud like projections 42 which extend radially from
22 the central portion 32 are angled such that they
23 extend further radially from the central portion 32
24 as they extend towards the rear 40 of the central
25 portion 32, this inclination allowing the soft
26 tissue anchor 30 to pass more easily into the soft
27 tissue.

28
29 A recessed portion 44 is positioned toward the rear
30 end 40 of the central portion 32 to facilitate
31 attachment of the suspending means 20 to the soft
32 tissue anchor 30.

1 The suspending means 30 may be respectively attached
2 to the soft tissue anchor 30 at this recessed point
3 44 by crimping a tube around the suspending means 20
4 to fix the suspending means 20 to the soft tissue
5 anchor 30.

6
7 In the embodiment shown the soft tissue anchor may
8 be suitably positioned in the rectus sheath 120
9 using an introducing tool 50. As shown in figure 15
10 the tool 50 comprises a handle 52 and elongate body
11 54. The elongate body 54 is curved through an angle
12 of approximately 30° to facilitate positioning of
13 the soft tissue anchor 30 in the rectus sheath or
14 surrounding soft tissue of the human body from an
15 incision in the upper wall of the vagina (as
16 described below). The soft tissue anchor 30 is
17 located on the elongate body at a narrowed portion
18 58 of the introducing tool such that the soft tissue
19 anchor is held in place by an abutment 56 such that
20 the narrowed portion 58 may extend through the
21 hollow portion 48 of the soft tissue anchor 30 such
22 that the point 60 of the insertion tool 50 protrudes
23 from the first end 38 of the soft tissue anchor and
24 allows the soft tissue anchor to be inserted into
25 the human body through the soft tissues and more
26 specifically through the rectus sheath 120 during
27 the placement of the soft tissue anchor.

28
29 The placement of the soft tissue anchor 30 on the
30 insertion tool 50 is shown in figure 8B and 8C,
31 which shows the soft tissue anchor 30 being pushed
32 through soft tissue fascia, such as the rectus

1 sheath 120. Once the soft tissue anchor has
2 penetrated the rectus sheath fascia 120, as shown in
3 Figure 8B, the introducing tool 50 can be withdrawn,
4 as shown in Figure 8C, leaving the soft tissue
5 anchor 30 in place.

6
7 As shown in figure 9 the soft tissue anchor may
8 alternatively be comprised of a central portion 70
9 and a plurality of projections 72 the projections
10 extending radially from the central portion 70 and
11 arranged along a substantial portion of the length
12 of the central portion 70. The projections 72 may
13 be of any shape such that they provide resistance
14 within the fibro-fatty soft tissue and blood tissues
15 of the para-urethral tunnel in the direction
16 opposite to that in which the soft tissue anchor is
17 introduced.

18
19 This resistance is also provided by the multiple
20 layers, typically between 5-10 layers of projections
21 72 which extend from the central portion 70.

22
23 Using these multiple layers of projections 72 it is
24 not necessary to insert the soft tissue anchor
25 through the rectus sheath 120. Instead the soft
26 tissue anchor should be positioned as high in the
27 retropubic space as possible in the fibro-fatty soft
28 tissue.

29
30 In the embodiment of the soft tissue anchor
31 comprising multiple layers of projections 72 which
32 resembles a christmas tree, as shown in figure 10,

1 the introducing tool comprises a collar which
2 releasably retains the projections during insertion
3 into the retropubic space. The collar may comprise
4 a semi-sharp bevelled needle. Following insertion
5 of the christmas tree like anchor into the fibro-
6 fatty soft tissue of the retropubic space the
7 introducing tool is withdrawn removing the collar
8 from around the plurality of projections 72 of the
9 soft tissue anchor, which due to their memory expand
10 outwards from the central portion 70 and grip the
11 fibro-fatty soft tissue of the retropubic space at
12 multiple layers. The collar of the introducing tool
13 which extends around the soft tissue may contain a
14 cross-sectional opening such that once the tool is
15 withdrawn the collar may be removed from the
16 surgical implant by passing the implant through the
17 cross-sectional opening.

18
19 Accordingly the invention also provides an
20 introducing tool for use in inserting the soft
21 tissue anchor.

22
23 Suspending means 20 attached to the soft tissue
24 anchors are formed from a strip of plastics material
25 such as polypropylene which is sufficiently soft to
26 avoid damaging the urethra or surrounding body
27 tissue and suitably inert such that it can be left
28 in the human body for a long period of time without
29 causing adverse reactions. Again, other suitable
30 materials will be apparent to those skilled in the
31 art.

32

1 The polypropylene mesh strip of 3-5mm in width which
2 forms the suspending means 20 has smooth edges to
3 avoid adhesion of the soft tissue to the strip,
4 reducing problems associated with leaving foreign
5 material in the human body for long periods of time.
6 As shown in figure 16 the polypropylene mesh strip
7 further comprises pores or pits 80 ranging in width
8 across the surface of the strip from 50 μ m to 200 μ m,
9 which extend through the strip from a first surface
10 of the strip 26 to a second opposite surface 28 of
11 the strip the pores 80 allowing tissue in-growth to
12 secure the suspending means 20 in the body.

13
14 The pores 80 are created by post synthesis treatment
15 of the polypropylene mesh material by a laser.

16
17 The polypropylene mesh which forms the suspending
18 means 20 also comprises microgrooves 82 of width 5 μ m
19 and of depth 5 μ m on the surfaces of the
20 polypropylene mesh.

21
22 The microgrooves 82 are aligned such that they are
23 substantially parallel with each other and separated
24 by ridges of around 5 μ m in width.

25
26 The ridges are formed by square pillars the base of
27 the microgroove being substantially perpendicular to
28 the square pillars or bevelled in relation to the
29 pillars. The microgrooving 82 being present on both
30 surfaces of the suspending means to orientate and
31 align the proliferating fibroblasts on the surface
32 of the plastics material and cause axial alignment

1 of collagen fibres and formation of at least one
2 strong ordered neoligament.

3

4 This orientation and alignment of the proliferating
5 cells adding mechanical strength to the tissue which
6 forms around the plastics material such that it is
7 more able to support the urethra.

8

9 The suburethral support is not provided with pores,
10 pits or grooves to discourage the formation of peri-
11 urethral adhesions.

12

13 Once the soft tissue anchors have been suitably
14 positioned in either the soft tissue of the para-
15 urethral tunnel or through the rectus sheath 120 the
16 length of the suspending means 20 can be altered
17 such that the suburethral support 10 hangs loosely
18 under the urethra.

19

20 As shown in figure 2 the suspending means 20 are
21 attached at a first end 22, 24 to the sides 12, 14
22 of the suburethral support 10, which extend on
23 either side of the urethra.

24

25 As shown in figure 6 a preferred method of altering
26 the length of the suspending means 20 attached to
27 the suburethral support 10 comprises a tunnelled
28 element 13 at each of the free ends 22, 24 of the
29 suburethral support 10 on either side of the
30 urethra. The tunnelled element 13 extends from the
31 edges of the suburethral support 10 to an aperture
32 15, the aperture being present on the opposite

1 surface 16 of the suburethral support 10 to the
2 surface which contacts the urethra 17, the aperture
3 15 having an edge 18 able to co-operate with a ring
4 element 19 such that the ring element which has
5 memory can be pushed onto the edge 18 of the
6 aperture 15 trapping the suspending means 20 between
7 the edge of the aperture 18 and the ring element 19
8 thus securing the suburethral support 10 along a
9 particular desired length of the suspending means 20
10 such that the suburethra support 10 hangs loosely
11 under the urethra.

12

13 Figure 5 shows an alternative method of attaching
14 the suspending means 20 to the suburethral support
15 10, the suspending means 20 being threaded through
16 jamming slots 12 such that the suspending means 20
17 are permanently attached to the jamming slots 12 by
18 being pulled into the jamming slots 12 as shown in
19 figure 5 such that the suspending means is held
20 tightly in position.

21

22 Alternatively as shown in figure 6 the suspending
23 means 20 may be passed through slots and the
24 suspending means permanently attached to the slots
25 by tying.

26

27 In use, as shown in figure 12 the soft tissue anchor
28 30 is placed on the introducing tool 50 as described
29 above. An incision 117 is made in the upper wall
30 116 of the vagina, as shown in Figure 11, and the
31 introducing tool 112 is passed through the incision
32 117, past one side of the urethra 118, behind the

1 pubic bone 119 and into the rectus sheath 120. It
2 is apparent to the surgeon when the rectus sheath
3 120 has been penetrated as this stage of insertion
4 presents significant resistance. Once the head 58
5 of the introducing tool 50 and the soft tissue
6 anchor 30 have passed through the rectus sheath 120,
7 the resistance diminishes and the surgeon ceases to
8 insert the introducing tool 50.

9
10 The introducing tool 50 is retracted from the body
11 releasing the soft tissue anchor 30. Due to the
12 wing sections 34 on the central portion 32 of the
13 soft tissue anchor 30, the soft tissue anchor 30 is
14 retained by the rectus sheath 120 as the introducing
15 tool 50 is retracted. Thus, the suspending means
16 remains in the body, secured by the soft tissue
17 anchor which is opposed by the rectus sheath 120.

18
19 This procedure is repeated, with a second soft
20 tissue anchor 30 and suspending means 20, with the
21 introducing tool 50 being passed through the
22 incision 117 and past the other side of the urethra
23 118. Thus, two suspending means 20 are provided,
24 attached to the rectus sheath 120, one passing
25 either side of the urethra 118.

26
27 The suspending means 20 are passed through the
28 tunnelled elements 13 of the suburethral support 10,
29 and the suspending means 20 are pulled through the
30 aperture 15 until the suburethral support 10 is
31 positioned such that it passes under the urethra
32 118. The suspending means 20 are then fixed in

1 place by placing a ring element 19 over the edge 18
2 of the aperture 15 such that the suspending means
3 are trapped between the edge 18 and the ring element
4 19 securing them in place.

5
6 Alternatively as shown in figure 5 the suspending
7 means may be fixed in the attachment tabs by
8 threading them through jamming slots 12 or tying, as
9 described above. The optimal lengths of the
10 suspending means 20 are such that the suburethral
11 support 10 passes under the urethra 118, but exerts
12 no pressure on the urethra 118 unless the bladder
13 121 is displaced. The optimal positioning of the
14 suburethral support 20 is roughly as illustrated in
15 Figure 14. When the bladder is displaced, the
16 suburethral support 10 aids closure of the urethra
17 118, thus alleviating urinary incontinence.

18
19 In this example, a portion of the surgical implant
20 is impregnated with methylene blue, which is a
21 harmless water soluble dye. At the end of the
22 procedure a small amount of fluid is expelled from
23 the bladder 121. Should this fluid contain any
24 dissolved methylene blue, it is very likely that the
25 bladder has been perforated on placing the soft
26 tissue anchor 30. In this case, cystoscopy should
27 be carried out. If no methylene blue is present,
28 the need for cystoscopy is advantageously obviated.
29 Other suitable water-soluble dyes may, of course, be
30 used.

31

1 Referring to Figure 14, it can be appreciated that
2 the surgical implant of the present invention, when
3 inserted in the human body, may extend from the
4 rectus sheath 120, through the paraurethral space
5 130 on one side of the urethra 118, around the
6 urethra and back to the rectus sheath 120 on the
7 other side. In contrast, the prior art device
8 comprises a tape 200 that also extends through the
9 abdominal wall 127 and represents a far greater
10 implanted mass.

11
12 Referring to Figure 11, in use, the further
13 embodiment of soft tissue anchor illustrated in
14 figure 9 for placement in fibro-fatty soft tissue of
15 the retropubic space is placed on an introducing
16 tool. An incision 117 is made in the upper wall 116
17 of the vagina, as shown in Figure 11, and the
18 introducing tool 112 is passed through the incision
19 117, past one side of the urethra 118, and located
20 in the fibro-fatty soft tissue and blood vessels of
21 the para-urethral tunnel. In this case the surgeon
22 does not introduce the soft tissue anchor as far
23 into the body as described previously and the rectus
24 sheath 120 is not penetrated. Once the soft tissue
25 anchor has been suitably positioned in the soft
26 tissue the surgeon ceases to insert the introducing
27 tool and retracts the introducing tool from the body
28 releasing the projections of the soft tissue anchor
29 72. The release of the projections 72 of soft
30 tissue anchor by the introducing tool allows the
31 projections to grip the soft tissue surrounding the
32 soft tissue anchor and provide resistance to

1 movement of the soft tissue anchor in a direction
2 opposite to that which it was inserted.

3

4 This procedure is repeated, with a second soft
5 tissue anchor such that the projections 72 of the
6 soft tissue anchor also provide resistance to
7 movement of the soft tissue anchor in a direction
8 opposite to that which it was inserted the
9 introducing tool being passed through the incision
10 117 and past the other side of the urethra 118.

11

12 Thus, two suspending means 20 are provided, which
13 are held in the soft tissue comprising fibro-fatty
14 tissue and blood vessels.

15

16 As described above the suspending means 20 are
17 passed through the attachment tabs of the
18 suburethral support 10, and the suburethral support
19 10 positioned such that it passes under the urethra
20 118.

21

22 Again this device contrasts that described by the
23 prior art device in that it does not extend through
24 the abdominal wall 127 and does not represent as
25 much implanted mass.

26

27 Various embodiments of the present invention can be
28 envisaged within the scope of the invention, for
29 example the soft tissue anchor may comprise a cone
30 or a half cone such that a circular or semi-circular
31 base is provided as a retaining means to prevent
32 retraction of the soft tissue anchor in a direction

1 opposite to that in which it is inserted into the
2 tissue.

3

4 Alternatively the soft tissue anchor may comprises a
5 substantially flat or disc shaped head. In this case
6 the introducing tool may have a conical head with a
7 sharp point at its apex and a slot for receiving the
8 flat or disc shaped head.

9

10 In yet another example, the soft tissue anchor may
11 be formed of two sections. The upper section, i.e.
12 the portion of the anchor that forms the sharp point
13 10, may be made from an absorbable material, such as
14 polyglactin such that a sharp point is provided for
15 insertion of the anchor into the body, but this
16 sharp point is later absorbed by the body so as to
17 eliminate any discomfort or disadvantage caused by a
18 sharp pointed object being retained inside the body.

19

20 The soft tissue anchor may be made from metal, such
21 as titanium, as this is a hard material that can
22 easily be formed into the head having the sharp
23 point at its apex, and is sufficiently malleable to
24 provide a tube that may be crimped to the suspending
25 means.

1 **CLAIMS**

2

3 1. A surgical implant for supporting the urethra,
4 the implant comprising: a suburethral support
5 suspended between at least two soft tissue anchors
6 attached at either side of the suburethral support,
7 each soft tissue anchor having retaining means for
8 retaining each anchor in tissue and suspending means
9 for suspending each side of the suburethral support
10 from a soft tissue anchor such that, in use, the
11 suburethral support passes under the urethra and the
12 soft tissue anchor anchors the implant and does not
13 penetrate the lower abdominal wall.

14

15 2. A surgical implant as claimed in claim 1
16 wherein the soft tissue anchor comprises a central
17 portion and the retaining means includes at least
18 one wing section, the wing section being mounted on
19 a first end of the central portion by resilient
20 hinge means such that the wing section is moveable
21 between an open, resting position and a deflected
22 position such that in use, when the soft tissue
23 anchor device is inserted into the tissue the wing
24 section is pushed or held towards the central
25 portion in the deflected position to permit entry of
26 the soft tissue anchor into the tissue and through
27 the rectus sheath, wherein the wing section returns
28 to its open or resting position and prevents the
29 soft tissue anchor being removed from the rectus
30 sheath.

31

1 3. A surgical implant as claimed in claim 2
2 wherein the central portion of the soft tissue
3 anchor comprises a hollow passage through which an
4 introducing tool may be inserted.

5

6 4. A surgical implant as claimed in claims 2 or 3
7 wherein the soft tissue anchor comprises a plurality
8 of wing sections.

9

10 5. A surgical implant as claimed in claim 1
11 wherein the soft tissue anchor is capable of
12 anchoring in the retropubic area without penetrating
13 the rectus sheath.

14

15 6. A surgical implant as claimed in claim 1 or 5
16 wherein the soft tissue anchor comprises a central
17 portion and the retaining means includes a plurality
18 of projections, the projections, extending radially
19 from the central portion along a length of the
20 central portion allowing fixation at a plurality of
21 layers.

22

23 7. A surgical implant as claimed in claim 1
24 wherein the soft tissue anchor comprises a
25 substantially flat head the bottom surface nearest
26 the suspending means of the flat head providing the
27 retaining means, which in use, anchors the implant
28 in the rectus sheath.

29

30 8. A surgical implant as claimed in claim 1
31 wherein the soft tissue anchor comprises a sharp
32 point allowing it to pierce or penetrate the rectus

1 sheath, and the retaining means comprises a surface
2 or protrusion directed rearwardly with respect to
3 the sharp point to maintain the anchor within the
4 rectus sheath.

5

6 9. A surgical implant as claimed in any preceding
7 claim wherein the soft tissue anchor is comprised of
8 plastics material.

9

10 10. A surgical implant as claimed in any preceding
11 claim wherein the soft tissue anchor is comprised of
12 polypropylene.

13

14 11. A surgical implant as claimed in any preceding
15 claim wherein the soft tissue anchor is integral
16 with the suspending means.

17

18 12. A surgical implant as claimed in any preceding
19 claim wherein the suburethral support is comprised
20 of flat polymer tape.

21

22 13. A surgical implant as claimed in any preceding
23 claim wherein the suburethral support has dimensions
24 of length 15-35mm, width 5-15mm and thickness 50-
25 350 μ m.

26

27 14. A surgical implant as claimed in any preceding
28 claim wherein the length of the suspending means is
29 adjustable.

30

1 15. A surgical implant as claimed in any preceding
2 claim wherein the suspending means comprise a
3 plastics strip, 3-5mm in width.

4
5 16. A surgical implant as claimed in any preceding
6 claim wherein the suspending means comprises a
7 plastics material which comprises pores which extend
8 through the plastics material from a first surface
9 of the plastics material to a second opposite
10 surface of the plastics material said pores ranging
11 in width across the surface of the plastics material
12 from 50 μ m to 200 μ m.

13
14 17. A surgical implant as claimed in any preceding
15 claim wherein the plastics material which comprises
16 the suspending means comprises pits, that indent but
17 do not extend through the plastics material, on at
18 least one of the surfaces of the plastics material,
19 the pits ranging in width from 50 μ m to 200 μ m.

20
21 18. A surgical implant as claimed in any preceding
22 claim wherein the suspending means is provided with
23 a plurality of microgrooves of width between 0.5-7 μ m
24 and of depth 0.25-7 μ m on at least one surface of the
25 plastics strip.

26
27 19. A surgical implant as claimed in claim 18
28 wherein the plurality of microgrooves are aligned
29 such that they are substantially parallel with each
30 other.

31

1 20. A method of supporting the urethra comprising
2 the steps of, introducing a surgical implant in any
3 of the preceding claims into an incision made on the
4 upper wall of the vagina, inserting a soft tissue
5 anchor on a first side of the urethra behind the
6 pubic bone, inserting a second soft tissue anchor on
7 a second side of the urethra behind the pubic bone,
8 such that the suburethral support is suspended from
9 the soft tissue anchor and supports the urethra.

10

11 21. Use of a method of supporting the urethra as
12 claimed in claim 20 in treating urinary incontinence
13 or uterovaginal prolapse.

14

15 22. A method as claimed in claim 20 wherein the
16 soft tissue anchors are inserted in the rectus
17 sheath.

18

19 23. A method as claimed in claim 20 wherein the
20 soft tissue anchors are inserted in the fibro-fatty
21 soft tissue which comprise the retropubic space and
22 do not penetrate the rectus sheath.

23

24 24. A surgical implant as claimed in any of claims
25 1 to 19 wherein at least a part of the surgical
26 implant of the present invention is coated or
27 impregnated with a water soluble dye.

28

29 25. A soft tissue anchor comprising a central
30 portion and retaining means wherein the retaining
31 means includes a plurality of projections, the
32 projections extending radially from the central

1 portion along a substantial portion of the length of
2 the central portion allowing fixation of the anchor
3 at a plurality of layers.

4

5 26. Use of a soft tissue anchor as claimed in claim
6 25 in plastic surgery, cosmetic surgery, hernia
7 repair, facelifts and the like.

8

9 27. Use of a plastics material as claimed herein in
10 implants to encourage cell through growth or
11 ingrowth.

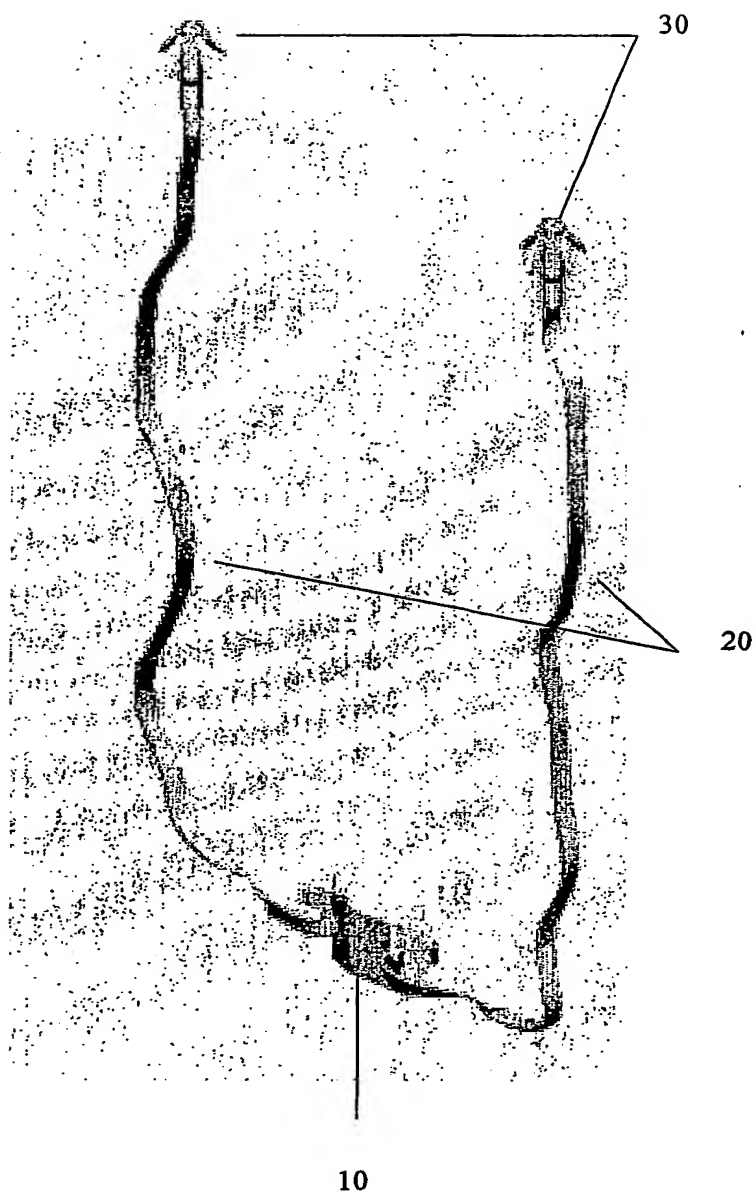


Figure 1

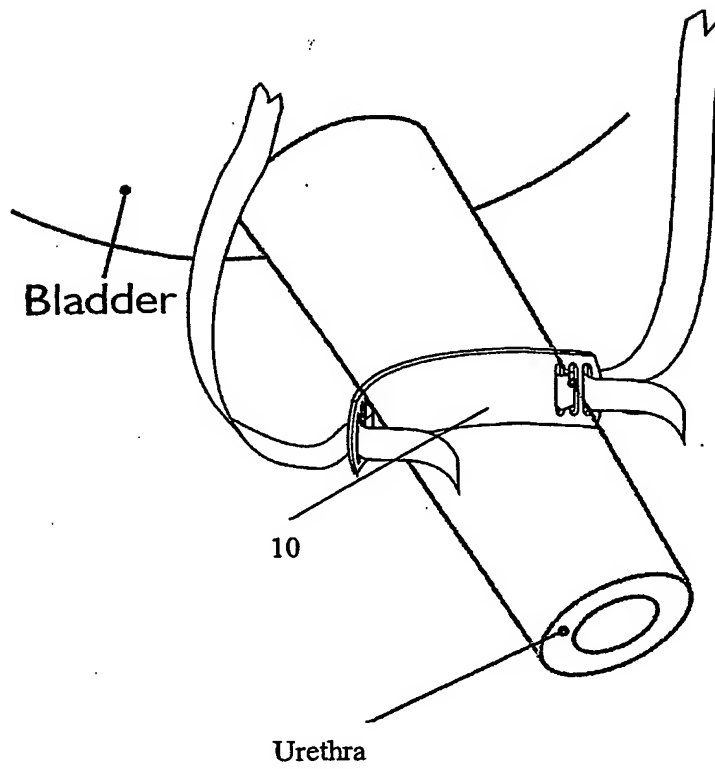
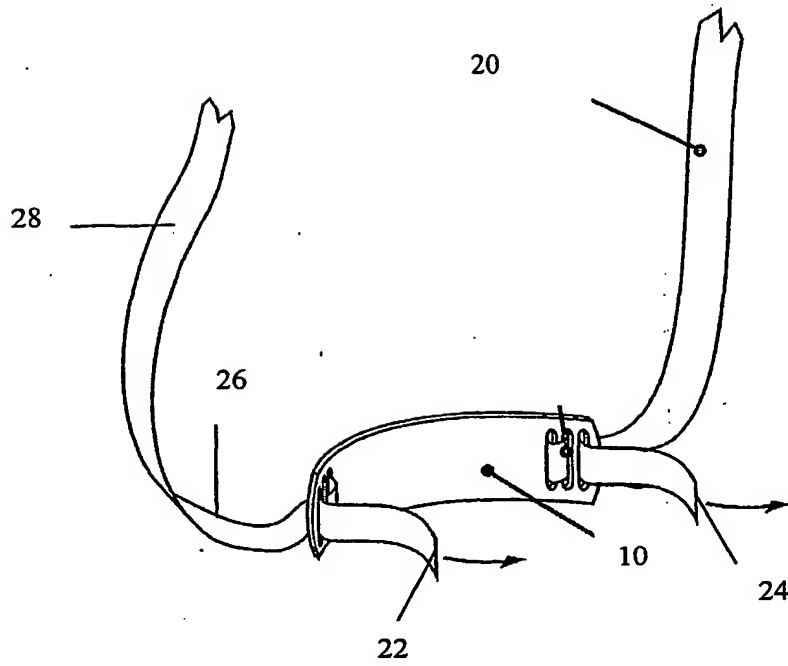


Figure 2

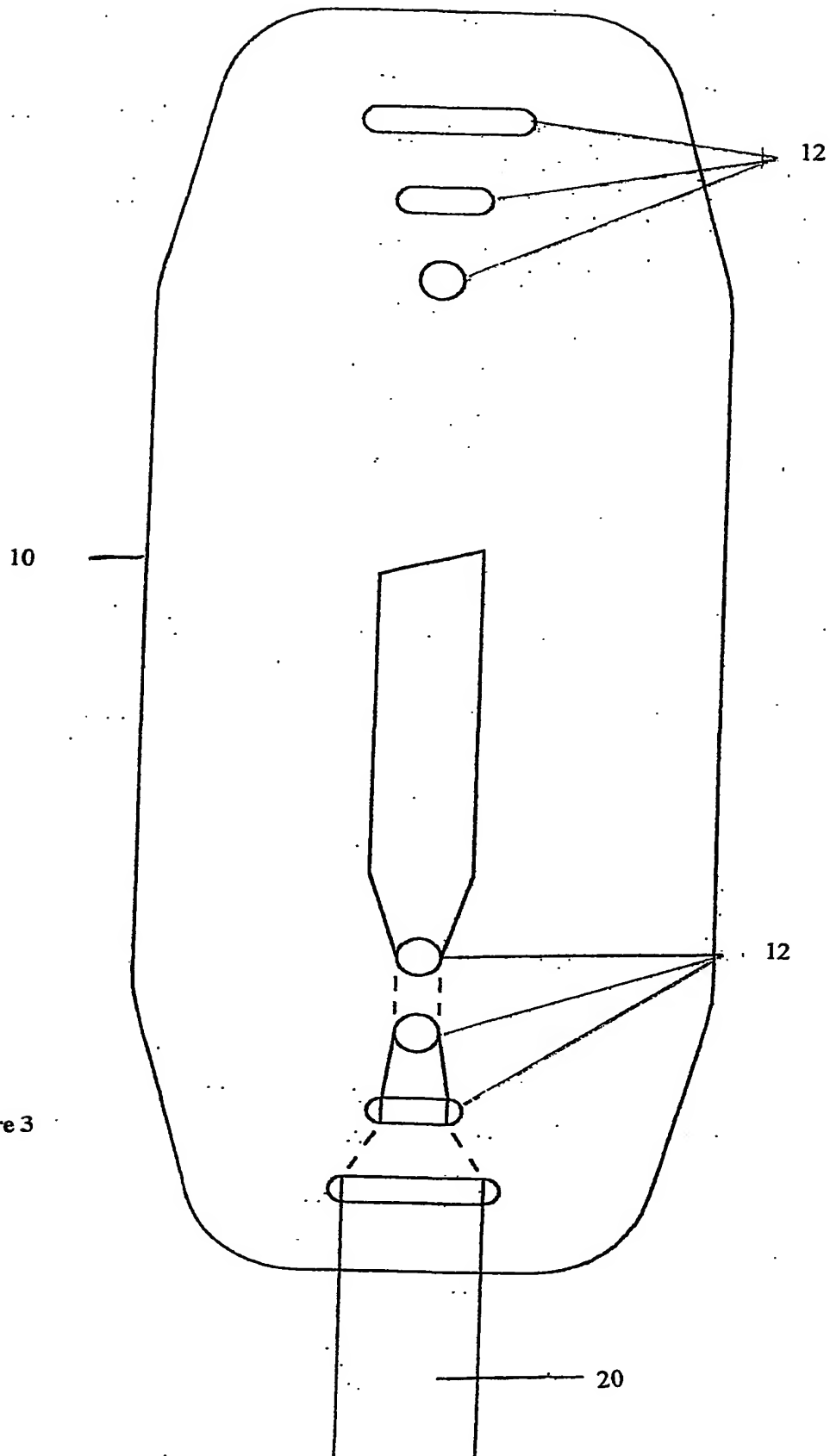


Figure 3

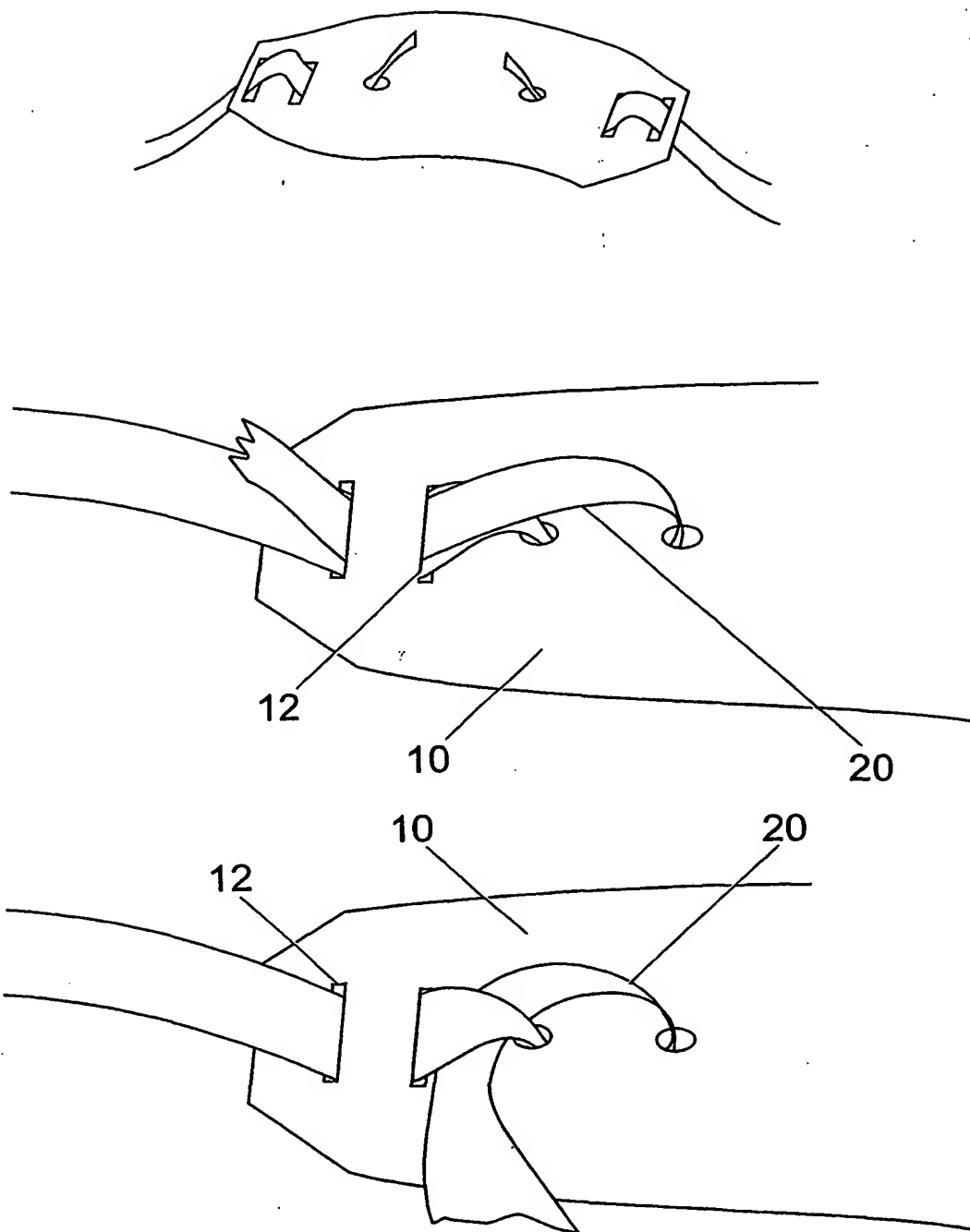


Fig. 4

Figure 5

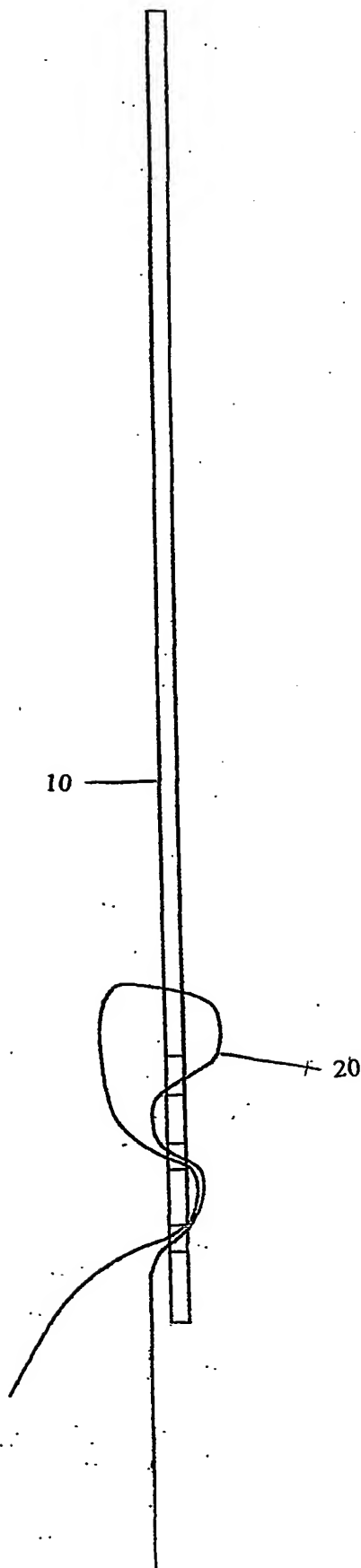


Figure 6A

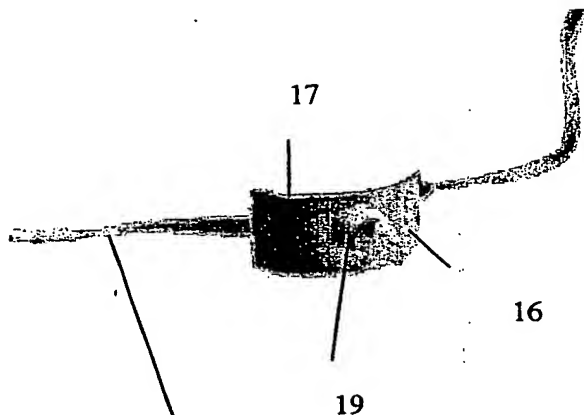


Figure 6B

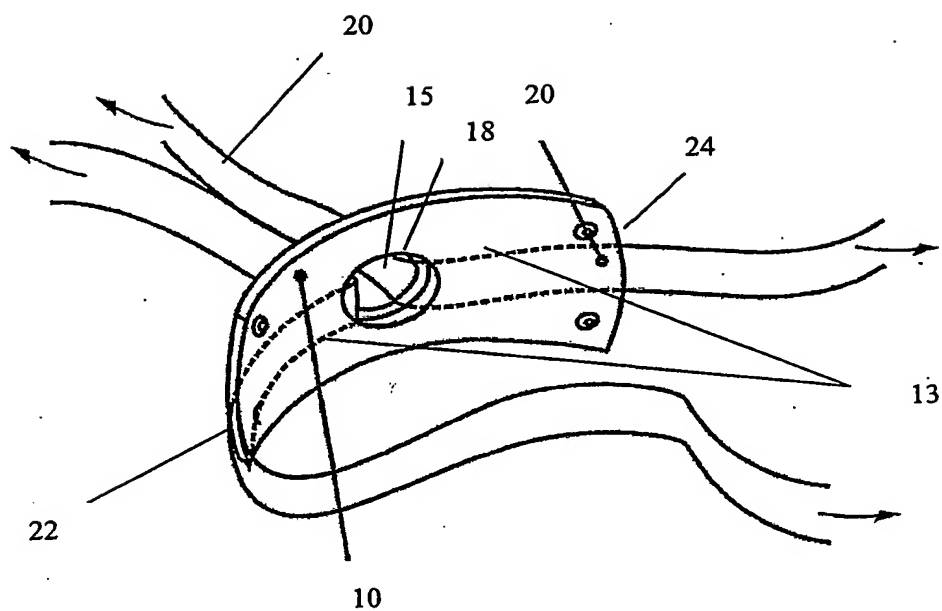


Figure 6C

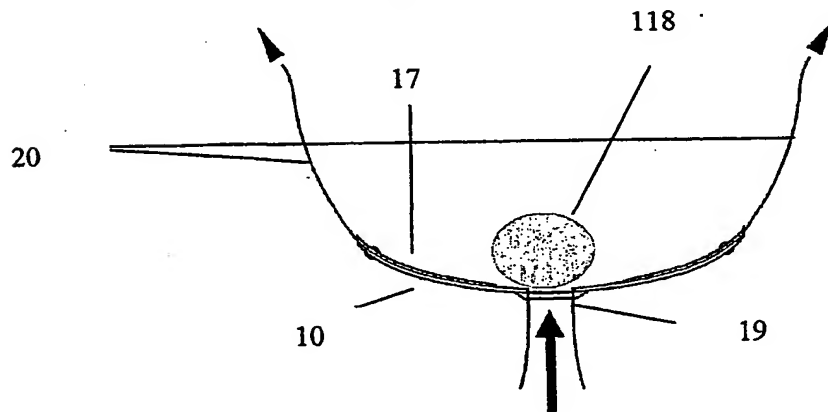


Figure 7A

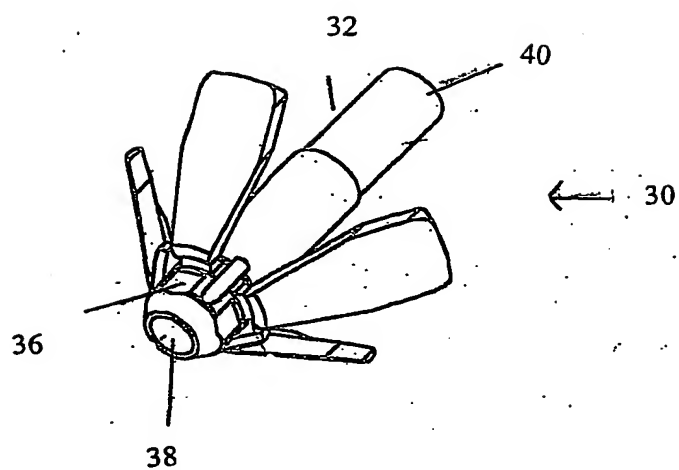


Figure 7B

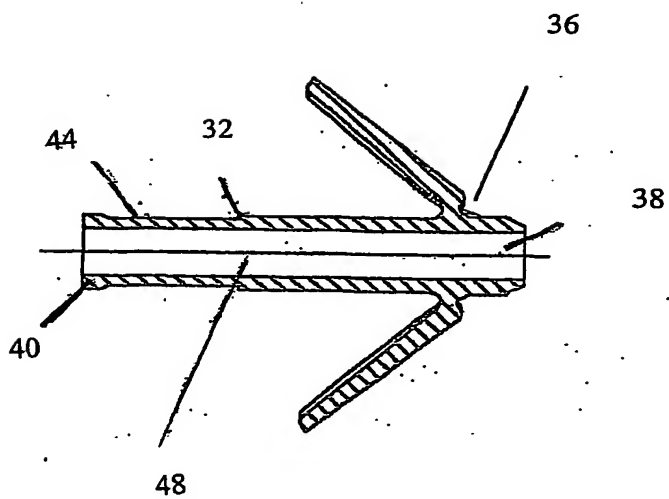


Figure 7C

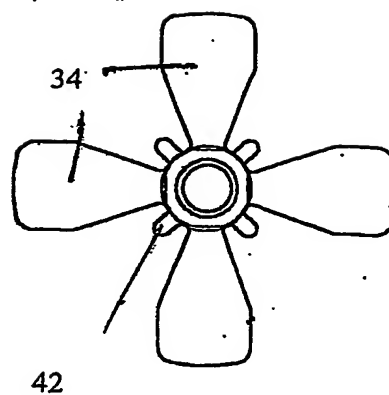


Figure 8A

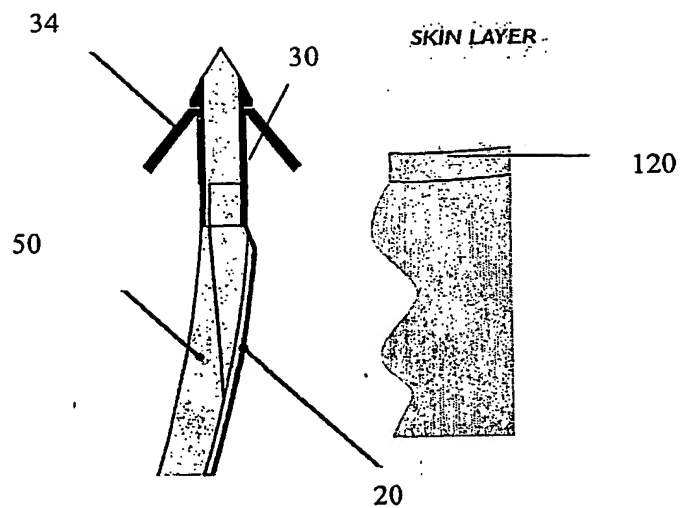


Figure 8B

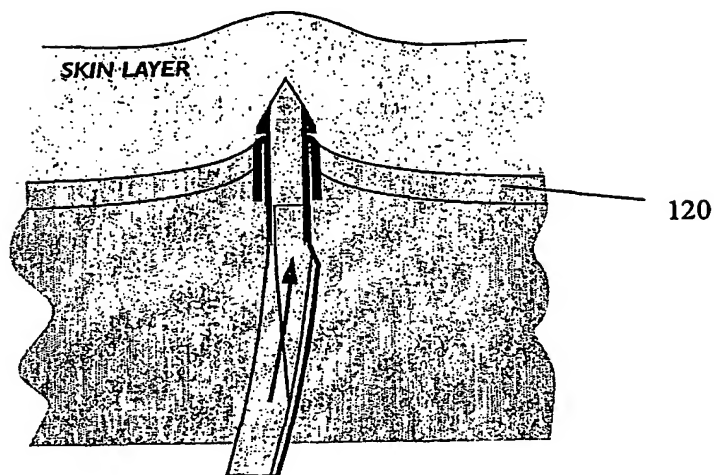


Figure 8C

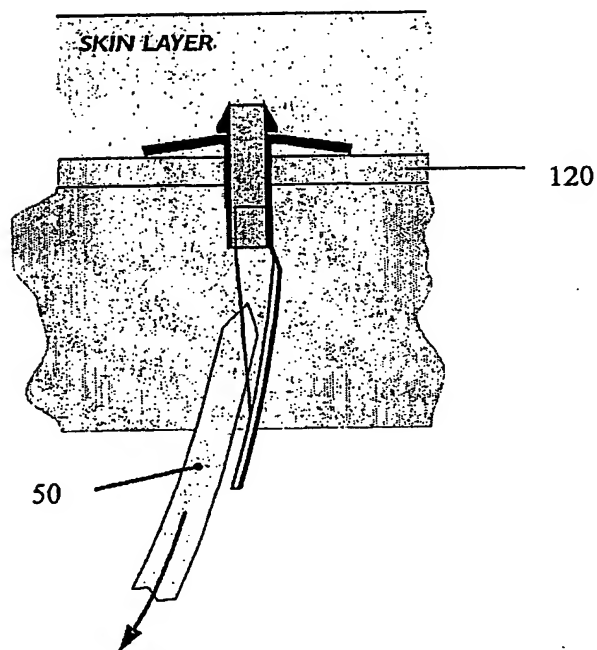


Figure 9

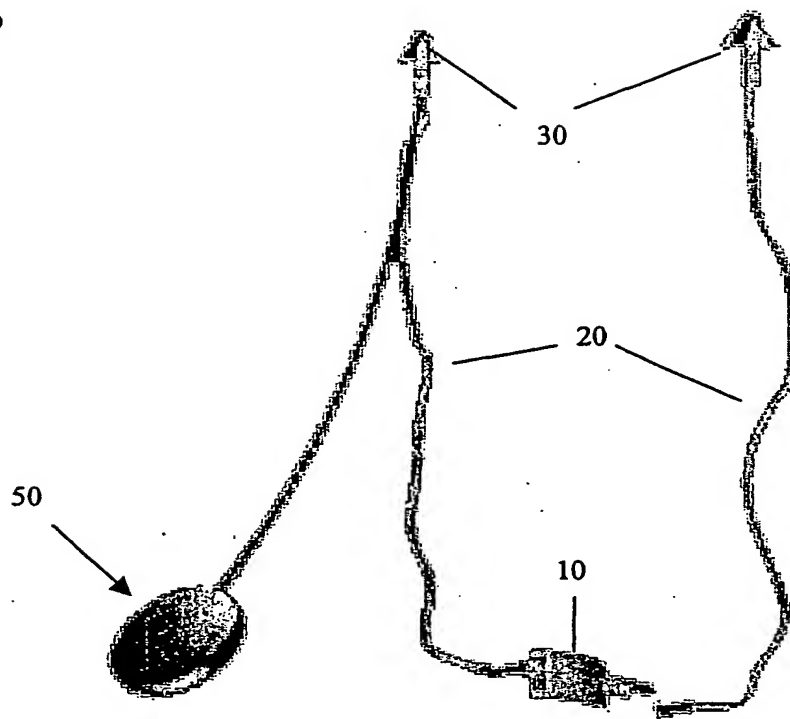
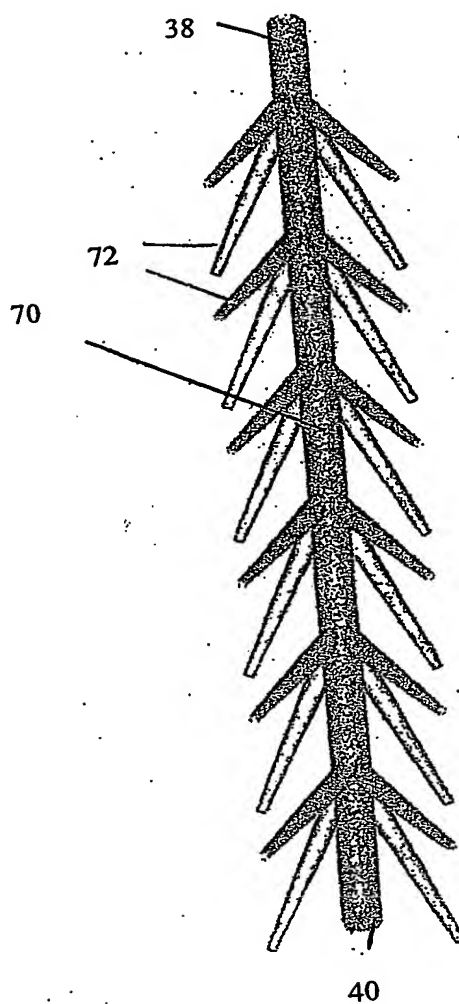


Figure 10

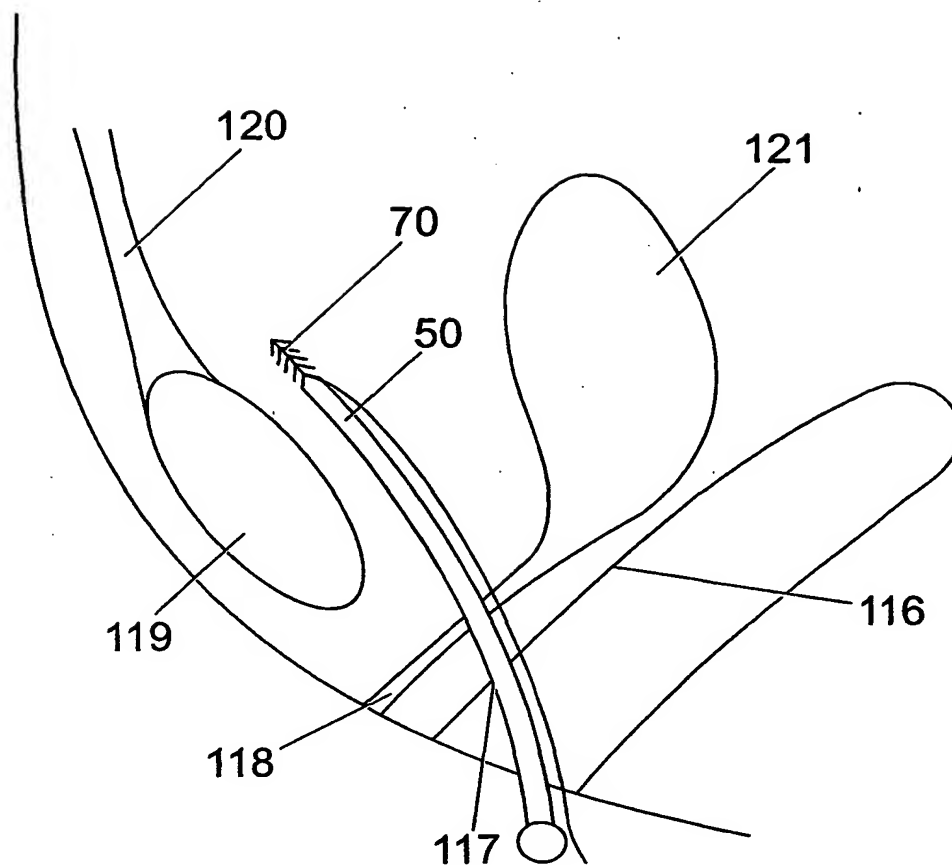
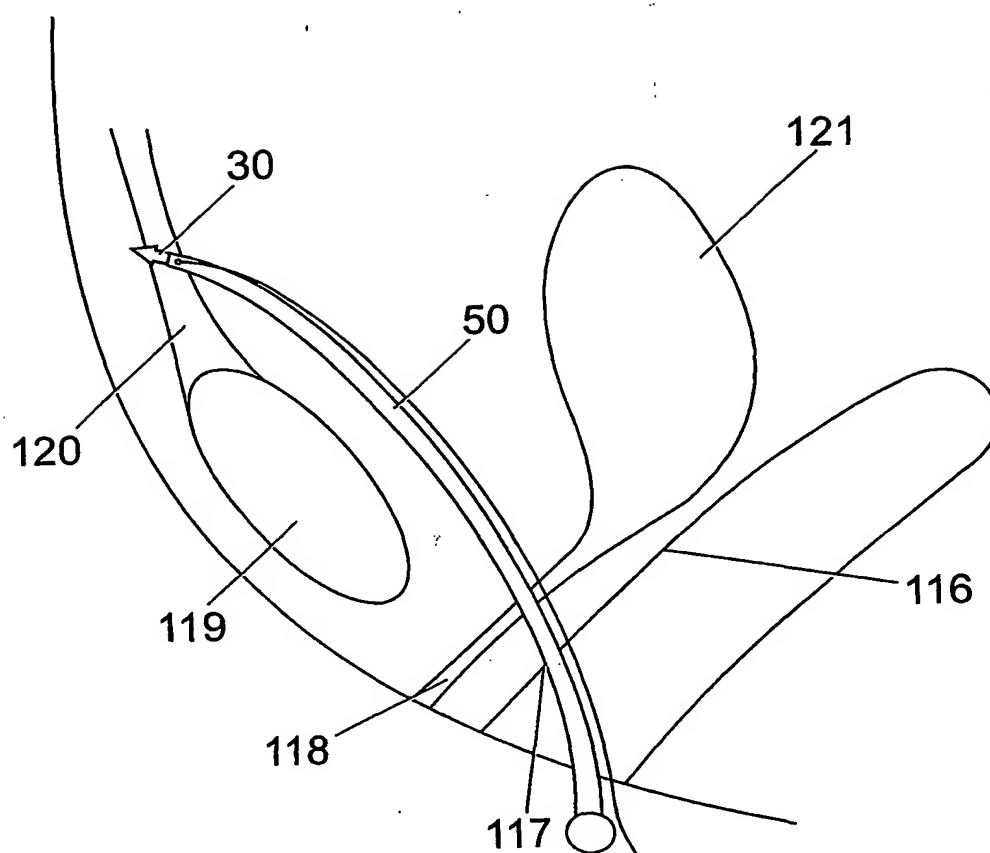


Fig. 11

*Fig. 12*

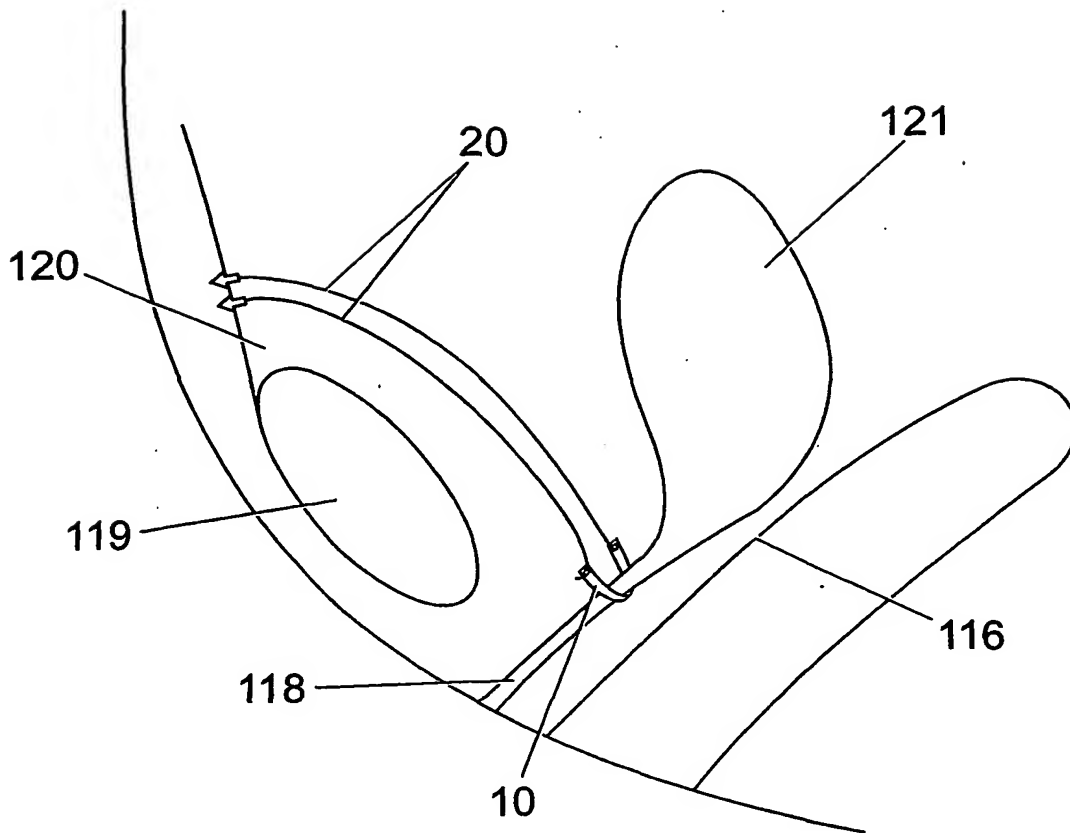


Fig. 13

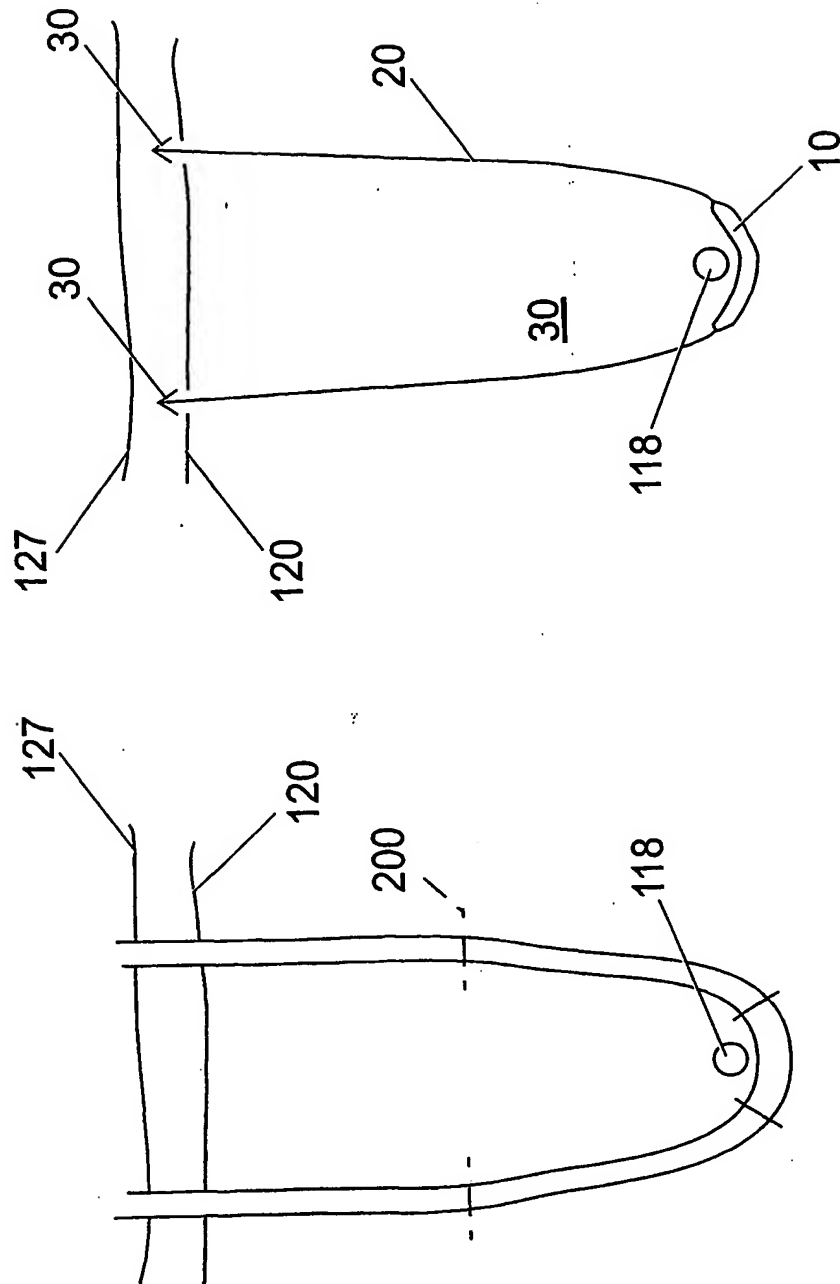


Fig. 14

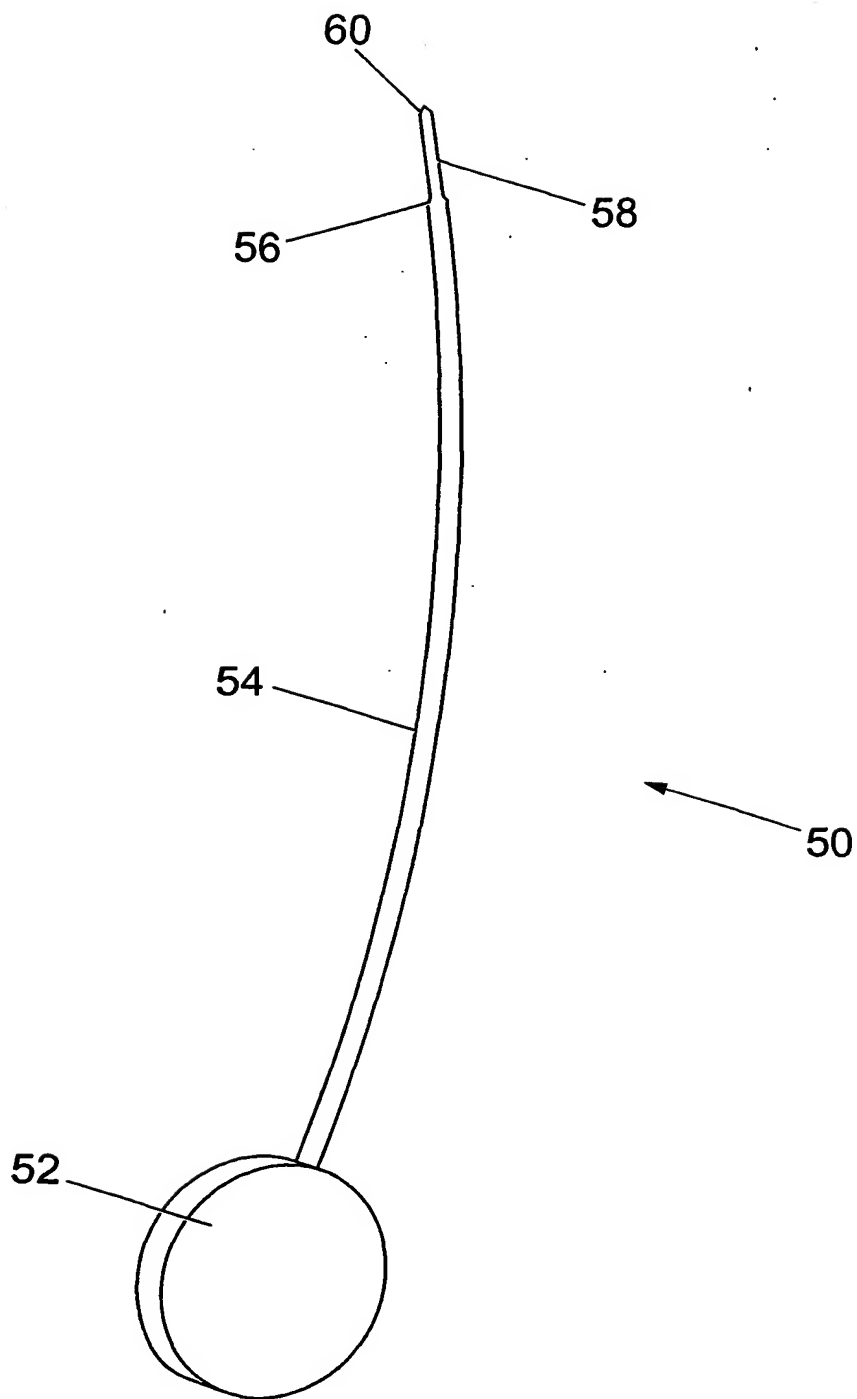
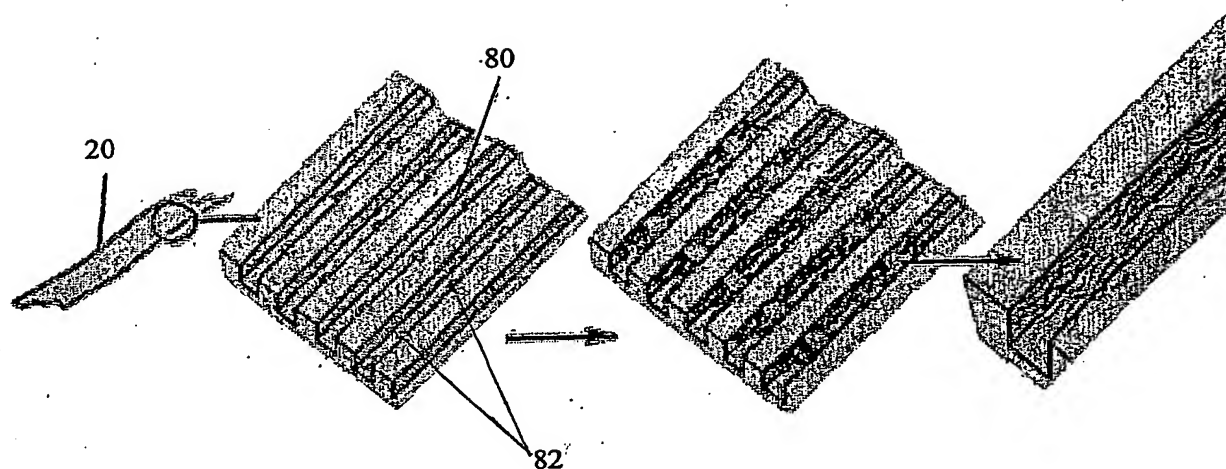
*Fig. 15*

Figure 16



INTERNATIONAL SEARCH REPORT

Inte: Application No

PCT/01/04554

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B17/04 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Date of the actual completion of the international search

22 January 2002

Date of mailing of the international search report

29/01/2002

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 NL - 2280 HV Rijswijk
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